EXHIBIT A

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO: Track One Cases MDL NO. 2804

Civ. No. 1:17-md-02804-DAP

HON. JUDGE DAN A. POLSTER

OMNIBUS MEMORANDUM OF LAW IN SUPPORT OF DISTRIBUTOR DEFENDANTS' MOTIONS IN LIMINE

I. INTRODUCTION

The Omnibus Memorandum Of Law In Support Of All Track One Bellwether Trial Defendants' Motions In Limine contains an overview of the controlling law governing motions in limine. AmerisourceBergen, Cardinal Health, McKesson, and Henry Schein (collectively, "Distributors") incorporate that discussion here.

II. IN LIMINE RULINGS REQUESTED

1. [D-1] The Court Should Preclude Plaintiffs From Offering Evidence Of, Or Arguments About, Distributors' Settlements With The DEA And West Virginia

Between 2007 and 2017, AmerisourceBergen Drug Corporation ("ABDC"), Cardinal Health, and McKesson each entered into one or more settlement agreements with the U.S. Drug Enforcement Administration. They also entered into settlements with the State of West Virginia in 2017 and 2019. Throughout this litigation, Plaintiffs have repeatedly cited these civil and administrative settlement agreements as evidence that Distributors failed to comply with a purported duty to report and block suspicious orders and, as a consequence, Defendants are liable to Plaintiffs. The Court should exclude any evidence of, reference to, or arguments about these settlements because they are inadmissible under (1) Rule 408 of the Federal Rules of Evidence, which prohibits the use of settlement evidence to prove the validity of disputed claims, (2) Rules 401 and 402, because they irrelevant since they do not concern Distributor facilities that serviced Summit and Cuyahoga counties, and (3) Rule 403, because the any minimal probative value the settlements might have (and there is none) is far outweighed by the unfair prejudice that would result if the jury were exposed to these settlements.

Background. In every iteration of their Complaints, Plaintiffs allege that Distributors did not maintain effective controls against diversion in connection with their distribution of controlled substances to pharmacies in Cuyahoga and Summit counties. More recently, in their

Motion for Partial Summary Adjudication That Defendants Did Not Comply With Their Duties Under The Federal Controlled Substances Act (Dkt. No. 1910), Plaintiffs sought a ruling that Distributors violated certain duties under the Controlled Substances Act ("CSA") and implementing regulations—in particular, 21 C.F.R. § 1301.74—regarding suspicious order monitoring. *See* Plaintiffs' Mem. of Law (Dkt. No. 1910-1) at 2 (arguing that "[t]he Court can and should find, based on the undisputed evidence, that each of the Defendants repeatedly violated the Controlled Substances Act in their shipments to Summit and Cuyahoga Counties."). In support of that contention, Plaintiffs repeatedly cited Distributors' prior settlements with DEA. *See*, *e.g.*, Dkt. No. 1910-1 at 69-71, 81-82, 88, 93, 105-11, 113, 119-122.

Three of the six DEA settlements, however, contain no admissions of wrongdoing. Dkt. No. 1964-3 (Cardinal Health 2008 (Ex. 215)); Dkt. No. 1964-37 (McKesson 2008 (Ex. 249)); Dkt. No. 1964-86 (ABDC 2007 (Ex. 298)). Three others contain narrow admissions that do not implicate the Track One Plaintiffs or their claims. In its 2012 Memorandum of Agreement (MoA), "Cardinal admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate." Dkt. No. 1960-103 (Ex. 209) at 3. The 2012 MoA does not identify what those failures were, when or where they occurred, or whether the inadequacies were violations of the CSA. In its 2017 Settlement, McKesson acknowledged that "at various times" from January 2009 to January 2017 "it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 8942(a)(5)." Dkt. No. 1964-24 (Ex. 236). None of the settlements has anything to do with distributions of opioid medications to Cuyahoga or Summit pharmacies specifically, or to Ohio pharmacies generally.

The same is true of Cardinal Health's 2016 settlement with West Virginia, ABDC's 2017 settlement with West Virginia, and McKesson's 2019 settlement with West Virginia: they expressly disclaim any admission of wrongdoing.

The Settlements Are Inadmissible Under Rule 408. Admission of evidence or arguments about the settlements would contravene both the text and purpose of Rule 408, which "bars the admission of settlement agreements when offered 'to prove or disprove the validity or amount of a disputed claim." *United States v. Tevis*, 593 F. App'x 473, 476 (6th Cir. 2015) (quoting Fed. R. Evid. 408(a)(1) (evidence of "accepting . . . a valuable consideration in compromising . . . [a] claim" is "not admissible . . . to prove . . . the validity or amount of a disputed claim")); 2 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence* § 408.03[5] (2d ed. 2017) ("Rule 408 applies . . . to completed compromises when offered against a compromiser."). "The purpose of this rule is to encourage settlements which would be discouraged if such evidence were admissible." Fed. R. Evid. 408 advisory committee notes, 1974 Enactment; *see Eid v. Saint-Gobain Abrasives, Inc.*, 377 F. App'x 438, 444 (6th Cir. 2010).

Under Rule 408, evidence of both the existence and content of prior settlement agreements is inadmissible for purposes of proving liability on a later civil claim. For example, in *Hobart Corporation v. Dayton Power & Light Co.*, No. 3:13-cv-115, 2017 WL 5956911 (S.D. Ohio Nov. 30, 2017), the court rejected plaintiffs' effort to establish that the defendant had assumed certain environmental liabilities because its corporate predecessor had made certain "admission[s]" in a settlement agreement resolving a separate case involving a different site. *Id.* at *19-20. Because the plaintiffs were "attempting to use evidence of a prior settlement agreement to establish . . . liability and prove the validity of a disputed . . . claim," the court held that the evidence was "inadmissible under Rule 408." *Id.* at *21. As the court explained,

"making the content of prior settlement agreements available for use in related litigation contravenes the very purpose of Rule 408." *Id*.

Likewise, in *Massachusetts Mutual Life Insurance Co. v. DLJ Mortgage Capital, Inc.*, 251 F. Supp. 3d 329 (D. Mass. 2017), the court precluded the plaintiff from relying on "certain facts set forth and acknowledged by Credit Suisse in a settlement agreement" with the Department of Justice to establish liability. *Id.* at 331. "[T]he letter, policy, and development of Rule 408" demonstrated that the DOJ settlement agreement, including the statement of facts expressly acknowledged by Credit Suisse therein, was "inadmissible" to establish liability. *Id.* at 332; *see also*, *e.g.*, *City of Mishawaka v. Uniroyal Holding, Inc.*, No. 3:04-cv-125, 2009 WL 499105, at *5 (N.D. Ind. Feb. 26, 2009) (rejecting plaintiff's attempt to use "prior settlement agreements" to "establish . . . liability by admission" because such a use of the agreements would be "precisely for the reasons prohibited by [Rule 408]").

Plaintiffs here clearly intend to rely on the settlements to prove Distributors' alleged failure to maintain adequate controls against diversion. *See*, *e.g.*, Plaintiffs' Mem. of Law (Dkt. No. 1910-1) at 20 (arguing that "a finding from this Court" that Distributors "shipped opioids in violation of the CSA has consequences for particular elements of many of Plaintiffs' claims"). Because the settlements represent the acceptance of a compromise of disputed claims, Plaintiffs' attempt to use the settlements to establish liability in the present cases is barred by Rule 408. That is reason enough to bar any evidence of, reference to, or arguments about the settlements.

The Settlements Are Irrelevant Under Rules 401 And 402. The settlements also are irrelevant to Plaintiffs' claims and, therefore, are inadmissible under Rules 401 and 402. To

Although Plaintiffs do not offer settlements for purposes of establishing the amount of damages they seek to recover, Rule 408 would bar their admission for that purpose as well. See Fed. R. Evid. 408(a)(1) (evidence of "accepting... a valuable consideration in compromising... [a] claim" is "not admissible... to prove... the validity or amount of a disputed claim") (emphasis added). Distributors reserve the right to object at trial if Plaintiffs seek to introduce the DEA Settlements to establish the amount of their claims or for any other purpose.

establish relevance, Plaintiffs must show that evidence of the settlements make any "fact . . . of consequence" in these cases "more or less probable than it would be without the evidence." Fed. R. Evid. 401 (test for relevant evidence); *see also* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."). To begin with, three of the six settlements with the DEA expressly disclaim any admission or concession of liability. Dkt. No. 1964-3 (Cardinal Health 2008 (Ex. 215)); Dkt. No. 1964-37 (McKesson 2008 (Ex. 249)); Dkt. No. 1964-86 (ABDC 2007 (Ex. 298)). Of the three agreements that do contain narrow admissions, *none* implicates distribution of opioids into Summit and Cuyahoga counties.

- Cardinal's 2012 MoA arose out of a DEA investigation of seven specific facilities in California, Colorado, Florida, Georgia, New Jersey, Texas, and Washington, Ex. 215 at 1-2—none of which distributes to Ohio pharmacies. The MoA mentions Cardinal Health's Ohio facilities only as part of a list of facilities not investigated. Ex. 215 at 13.
- McKesson's 2017 settlement contains allegations relating to twelve distribution centers, none of which is the New Castle, PA facility that services Summit and Cuyahoga counties. The settlement also does not identify any particular pharmacies or shipments in Ohio, nor are there any admissions concerning McKesson's operations in Ohio.
- Neither ABDC's April 19, 2007 Initial Suspension Order nor the June 22, 2007 Settlement Agreement contains allegations concerning distribution of opioid medications to Cuyahoga or Summit pharmacies specifically, or to Ohio pharmacies generally.

Similarly, Cardinal Health, ABDC, and McKesson's settlements with West Virginia neither admit fault nor concern shipments of prescription opioids to any place other than West Virginia.

And, notwithstanding the narrow admissions contained in three of the settlements, the agreements are not relevant, because any reference to them would necessarily depend on a "if it happened there, it must be happening here" premise—which is, as Plaintiffs have acknowledged, invalid. Dkt. No. 2212 at 9, 30 (citing *In re Chocolate Confectionary Antitrust Litig.*, 801 F.3d 383, 402 (3d Cir. 2015) (quoting Areeda & Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF

ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶ 1421a, at 160); *In re Elevator Antitrust Litig.*, 502 F.3d 47, 51-52 (2d Cir. 2007)).

The narrow admissions are also irrelevant because they do not establish any element of Plaintiffs' claims. For the RICO claims, Plaintiffs must establish (inter alia) a *knowing or intentional* violation of the CSA statute—and none of the settlements admits to any such knowing or intentional wrongdoing.² Similarly, for the nuisance claim, violation of the CSA is irrelevant because the CSA is not a safety statute.³

The Settlements Are Inadmissible Under Rule 403. Even if the settlements had some relevance (which they do not), they still would be inadmissible under Rule 403, which requires the exclusion of evidence "if its probative value is substantially outweighed" by the "danger" of "unfair prejudice" or "confusing the issues." Fed. R. Evid. 403. Admission of the settlements would unfairly prejudice the Distributors and cause jury confusion. As the Sixth Circuit has explained, "the potential impact of evidence regarding a settlement agreement with regard to a determination of liability is profound" and would, if allowed, undermine the "strong public interest' in encouraging settlement negotiations." *Stockman v. Oakcrest Dental Ctr., P.C.*, 480 F.3d 791, 800, 805 (6th Cir. 2007) (quoting *Goodyear Tire & Rubber Co. v. Chiles Power Supply, Inc.*, 332 F.3d 976, 980 (6th Cir. 2003)).

² 21 U.S.C. §§ 841, 843 ("[I]t shall be unlawful for any person knowingly or intentionally"); see 18 U.S.C. § 1961(1)(D) (predicate acts limited to "felonious" conduct).

³ Taylor v. City of Cincinnati, 143 Ohio St. 426, 433 (1944) (a statute is a "safety statute" only if it sets forth a "specific legal requirement for the protection" of the plaintiff and those similarly situated); see Opinion & Order (Dkt. No. 1680) at 24 (CSA "was not intended to protect [governments] from spending more on addiction-related public services").

⁴ Underscoring both the importance of the bar on the admission of settlement agreements, the Sixth Circuit has explained that the public interest in settlement negotiations would be undermined if settling parties enjoyed only thin "veneer of protection" offered by curative instructions. *Id.* at 805. The Court, accordingly, has "reject[ed] the proposition that any amount of evidence supporting liability, . . . coupled with a limiting instruction read at any time during the trial is sufficient to cure the wrongful admission" of settlement evidence. *Id.*; see also 2 Jack B. Weinstein & Margaret A. Berger, Weinstein's Federal Evidence § 408.11[1][a] (2d ed. 2017) ("The failure to

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

MDL 2804

OPIATE LITIGATION

Case No. 17-md-2804

This document relates to:

Hon. Dan Aaron Polster

Track One Cases

Plaintiffs' Omnibus Response to Defendants' Motions *In Limine* (Dkts. #2645, #2648, #2653, #2661, #2663, #2666, #2668) and Memorandum in Support

October 7, 2019

- B. PLAINTIFFS' RESPONSE TO OMNIBUS MEMORANDUM OF LAW IN SUPPORT OF DISTRIBUTOR DEFENDANTS' MOTIONS IN LIMINE (DKT. #2666).
 - 1. <u>Distributors' MIL No. D-1</u>: The Court should preclude Plaintiffs from offering evidence of, or arguments about, Distributors' settlements with the DEA and West Virginia.

Defendants have filed several motions *in limine* that seek to exclude evidence regarding their resolution of various enforcement actions taken by federal and state governments. The arguments asserted by Defendants in these MILs are very similar, so rather than repeat them in response to each MIL, Plaintiffs will address the legal standards and argument regarding these topics once, and will refer back to this argument on the specific points. If any specific additional information is necessary in response to a particular MIL, that will be addressed separately.

The argument and legal standards addressed here are applicable to the following MILs:

- Dkt. #2666 –Distributors' MIL No. D-1: Distributor settlements with the DEA and West Virginia.
- Dkt. #2645 Henry Schein MIL Nos. HS-9 and HS-10: DEA fines, investigations, and Ohio Board of Pharmacy cease and desist letter (*infra* at § C.9-10).
- Dkt. #2648 Walgreens' MIL No. W-2: DEA enforcement action and related settlement with Walgreens (*infra* at § D.2).
- Dkt. #2663-1 McKesson MIL No. MCK-4: Allegations contained in letters from the DEA and DOJ to McKesson (*infra* at § F.4).
- Dkt. #2668-1 Teva MIL No. TAD-1: Cephalon misdemeanor off-label promotion plea agreement (*infra* at § G.1).
- Dkt. #2668-1 Teva MIL No. TAD-3: Cephalon settlement with DOJ (infra at § G.3).

The agreements are not precluded by Rule 408. Federal Rule of Evidence 408 generally prohibits the use of evidence of statements or conduct to compromise a claim "to prove or disprove the validity or amount of a disputed claim." However, "Rule 408 only bars the use of compromise evidence to prove the validity or invalidity of the claim that was the subject of the compromise, not some other claim." Uforma/Shelby Bus. Forms, Inc. v. N.L.R.B., 111 F.3d 1284, 1293–94 (6th Cir. 1997) (citing Wright, et al., FEDERAL PRACTICE & PROCEDURE: EVIDENCE § 5314, 5308 (1st ed. 1980)

(internal citations omitted, emphasis added); *see also Gjokaj v. United States Steel Corp.*, 700 F. App'x 494, 501 (6th Cir. 2017). So Rule 408 does not even apply to the evidence Defendants seek to exclude, since that evidence does not involve the specific claims asserted by Cuyahoga and Summit Counties in this case.⁵⁵

Moreover, even when Rule 408 applies, evidence of settlements *is* admissible where it is offered for "another purpose," such as "proving a witness's bias or prejudice, negating a contention of undue delay, or proving an effort to obstruct a criminal investigation or prosecution." FED. R. EVID. 408(b). The burden of establishing the application of Rule 408 is on the party invoking its protection. *William F. Shea, LLC v. Bonutti Research, Inc.*, No. 2:10-CV-615, 2012 WL 5077701, at *5 (S.D. Ohio Oct. 18, 2012).

Rule 408 is therefore "not a blanket rule that wholly precludes the consideration of settlement discussions." *Homoki v. Rivers Edge Tree Stands*, No. 1:12-CV-2926, 2012 WL 6631043, at *2 (N.D. Ohio Dec. 19, 2012). Instead, "evidence of such discussions may be admitted for any purpose not specifically excluded by the Rule." *Id.* As the rule makes clear, a settlement may be admissible where "it is offered for a purpose other than to prove liability or disprove a claim." *In re:* E. I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig., No. 2:13-CV-170, 2016 WL 659112, at *54 (S.D. Ohio Feb. 17, 2016). Accordingly, "the principal inquiry that determines whether Rule 408 bars introduction of evidence of [this evidence] must be toward the purpose for which the evidence is being offered." *McAuliffe v. United States*, 514 F. App'x 542, 549 (6th Cir. 2013).

The Sixth Circuit and Ohio district courts have recognized several purposes allowing for the admission of settlement evidence. One such purpose is establishing a party's knowledge or notice of potential harm. *See E.I Du Pont*, 2016 WL 659112, at *54 (consent decree was properly admitted when it was offered "as evidence of [Defendant] DuPont's knowledge and/or notice of C-8's

This is also plain from the language of the rule, which repeatedly references "prov[ing] or disprov[ing] the validity or amount of <u>a</u> disputed claim" by offering evidence of conduct that occurred while attempting to resolve "<u>the</u> claim." *See* FED. R. EVID. 408(a)(1) and (2) (emphasis added).

potential for harm, not as evidence that DuPont acted negligently"). In this case, the multitude of enforcement actions and settlements establish a pattern of conduct demonstrating knowledge by Defendants that their SOM systems were inadequate and were likely to cause harm – not just in the specific locations where the enforcement actions focused, but throughout the country. That is particularly true in this case, where Defendants have claimed that they lacked understanding of their legal duties.

Another permissible purpose is to prove a party's state of mind. See Croskey v. BMW of North America, Inc., 532 F.3d 511, 519 (6th Cir. 2008) ("settlement evidence was not offered as a defense to plaintiff's negligence claims against BMW, but instead was offered to show the state of mind of the witnesses"); McAuliffe, 514 F. App'x at 549-50 ("It is plain from the record that the contents of the conversation were not offered in McAuliffe's criminal trial to prove the liability of either one in the civil dispute or the amount of those claims. Instead, the evidence was offered for the other purpose of showing McAuliffe's knowledge of and participation in illegal acts—in other words, his state of mind, which Rule 408 allows.").

With regard to Plaintiffs' nuisance claims, the Court identified as disputed issues of fact for trial in its rulings on the parties' motions for summary judgment: (1) whether a public nuisance exists (Dkt. #2572 at p. 4); (2) whether the opioid epidemic interferes with public health and public safety rights (Dkt. #2578 at p. 4); (3) whether Defendants' conduct substantially contributed to Plaintiffs' injuries (*id.* at p. 5); and (4) whether Defendants' conduct was intentional or unlawful (*id.* at pp. 5-7). The enforcement actions demonstrate that Defendants' conduct was intentional and persisted over a lengthy period of time, which goes to the heart of Plaintiffs' claims.

The agreements are admissible under Rule 406. Evidence of "an organization's routine practice . . . to prove that on a particular occasion the . . . organization acted in accordance with the . . . routine practice" is admissible. FED. R. EVID. 406; *CSX Transp., Inc. v. Exxon/Mobil Oil Corp.*, 401 F. Supp. 2d 813, 818 (N.D. Ohio 2005) (finding the evidence of performing inspections and "observations made during the inspections, [are] admissible under Fed. R. Evid. 406 as proof of habit or routine practice"). "Rule 406 evidence must rest on an analysis of instances numerous

enough to support an inference of systematic conduct and to establish one's regular response to a repeated specific situation." *Bell v. Consol. Rail Corp.*, 299 F. Supp. 2d 795, 800 (N.D. Ohio 2004) (internal citations and quotations omitted). Courts may consider three elements to determine whether the organization's routine practice is admissible under Rule 406: (1) whether "it is unlikely that the individual instance can be recalled or the person who performed it can be located," (2) whether the "specific conduct ... is engaged in frequently by the group," and (3) whether "the number of instances of such behavior [is] large enough that doubt about a single instance does not destroy the inference that the practice existed." *Martin v. Thrifty Rent A Car*, 145 F.3d 1332 (6th Cir. 1998).

Defendants' conduct that forms the bases of the DEA/DOJ agreements occurred "with sufficient regularity making it more probable than not that it would be carried out in every instance or in most instances." *Bell*, 299 F. Supp. 2d at 800. The agreements and related documents establish that Defendants engaged in "systematic, particularized, and repetitive conduct" by selling prescription opioids without proper, effective controls to prevent diversion and to identify, report, and stop shipment of suspicious orders. As the agreements describe, the temporal and geographic scope of this systematic conduct (covering millions of transactions) was so extensive that it cannot be evaluated by a singular instance, nor can a single instance destroy the inference that this was a routine practice.

Both Cardinal Health and McKesson agreed to pay significant fines in 2008 relating to their failure to comply with their obligations under the Controlled Substances Act. Despite agreeing to comply with those obligations, both companies continued to ignore them and were the subject of later enforcement actions by the federal government roughly a decade later, reflecting their persistent failure to conform their conduct to the law. In connection with those later enforcement actions, Cardinal and McKesson acknowledged that they had not lived up to their prior agreements. This history of repeated violations of their legal duties shows that Defendants' violations were not the result of mere oversight, but reflected Defendants' intentional and ongoing business practices.

As a result, the agreements are admissible under Rule 406 because they prove Defendants acted in accordance with their routine practice.

The agreements are relevant. Evidence is relevant where it "has any tendency to make a fact more or less probable than it would be without the evidence," and "the fact is of consequence in determining the action." FED. R. EVID. 401. Generally, "[r]elevant evidence is admissible" while "[i]rrelevant evidence is not admissible." FED. R. EVID. 402.

Defendants' meritless relevance arguments are wholly divorced from an analysis of the substantive law governing the claims and defenses at issue. The DEA/DOJ agreements are relevant evidence for several claims at issue. For instance, as part of Plaintiffs' RICO and Ohio Corrupt Practices Act (OCPA) claims against McKesson, Cardinal, and AmerisourceBergen, Plaintiffs seek to establish that these Defendants formed and operated an opioid supply chain to expand their sales of prescription opioids through repeated violations of the CSA. Defendants failed to maintain effective controls to prevent diversion and filled suspicious orders for opioids. The DEA/DOJ agreements describe investigations and findings by the DEA and the DOJ concerning the same violations alleged here. The agreements also describe the multiple suspension orders and ISOs which provided notice to Defendants that their suspicious order systems were ineffective and were being abused.

Evidence regarding Defendants' repeated violations of their duties under the CSA demonstrates that Defendants continued the conduct in the face of confirmed proof that such conduct was contributing to the opioid epidemic. These agreements are therefore relevant to establish Defendants' RICO and OCPA violations.

Distributor Defendants argue that the settlement agreements are not relevant because some of them "disclaim any admission or concession of liability," and even those that contain "narrow admissions" do not implicate the distribution of opioids into Summit and Cuyahoga Counties. Dkt. # 2666 at p. 5. Defendants therefore attempt to cabin the relevance of the agreements to the distribution centers at issue there. Yet, the agreements make it clear that they apply to all (or at least most) distribution centers. The McKesson 2017 Agreement, for example, expressly states that

"[t]his Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances." Dkt. #2212-29; Dkt. #2557-3. AmerisourceBergen's obligations are similarly not limited to any particular Distribution Centers.

These arguments also fail to acknowledge that the conduct about which Plaintiffs complain is not limited to conduct that occurred in Cuyahoga and Summit Counties. Instead, Plaintiffs' allege that the harm they suffered was caused by conduct that occurred all across the nation, over many years, which was a substantial factor in causing the nuisance condition that persists in those counties and also gives rise to Plaintiffs' other claims. This issue is discussed more fully in response to Walgreens' MIL No. W-2, *infra* at § D.2, regarding a 2007 DEA enforcement action in Florida, which explains how Defendants' failures to adequately monitor sales to prevent diversion in one geographic location affects other locations, including the Plaintiff counties.

The agreements are not unfairly prejudicial. Although relevant evidence is generally admissible, "Rule 403 carves out a narrow exception to this broad rule of admissibility." *United States v. Schrock*, 855 F.2d 327, 333 (6th Cir. 1988). Relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." *Id.*; FED. R. EVID. 403. As the permissive language of the rule makes clear, a court may admit evidence even where there is potential prejudice, and "[this] decision to admit relevant, but potentially prejudicial, evidence is committed to the sound discretion of the trial court." *Id.* "When the district court admits evidence over a party's undue-prejudice objection, [the 6th Circuit] review[s] the admitted evidence in the light most favorable to its proponent, maximizing its probative value and minimizing its prejudicial effect." *United States v. Asher*, 910 F.3d 854, 860 (6th Cir. 2018) (citation omitted).

Here, any danger of unfair prejudice or confusion is quite limited because the practices described in the DEA/DOJ agreements pertain directly to Defendants' controls to prevent diversion and the filling of suspicious orders for opioids. Thus, this evidence will not confuse the

issue nor inject extraneous factual matters into the trial. Nor would a jury be likely to take this evidence as a concession of liability – although the evidence is factually on point, the *legal* context of the agreements is so distinct that a jury is not likely to believe that an agreement with the government to settle what are in effect charges for CSA violations amount to an admission of liability to the alleged RICO, OCPA, and public nuisance claims. And, to the extent that the jury credits the factual statements in the agreements, this does not constitute "unfair" prejudice. Even if that were the case, the Court can ensure, through trial rulings and jury instructions, that the context in which the facts were developed does not overwhelm the import of the evidence itself.

For these reasons, Distributor Defendants' arguments that their distributor settlements with the DEA and West Virginia are irrelevant, prejudicial, or inadmissible under Rule 408, are without merit. Distributor Defendants' MIL No. D-1 should be denied.

2. <u>Distributors' MIL No. D-2</u>: The Court should preclude non-party corporate representatives from testifying to matters outside their personal knowledge.

Distributor Defendants broadly seek to preclude the admission of non-party 30(b)(6) witness testimony "on matters outside the witness' personal knowledge," arguing such evidence is inadmissible hearsay and lacks foundation. For the following reasons, Distributor Defendants' MIL No. D-2 should be denied.

Contrary to Distributor Defendants' assertion, Rule 602's personal knowledge requirement does not preclude the introduction of 30(b)(6) testimony at trial that is beyond the witness' direct personal knowledge. It is well established that a corporate designee testifying pursuant to Rule 30(b)(6) "does not testify as to his personal knowledge or perceptions [but rather] testifies 'vicariously,' for the corporation, as to its knowledge and perceptions." *Brazos River Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 434 (5th Cir. 2006). *See also Lloyd v. Midland Funding, LLC*, No. 15-5132, 639 Fed. Appx. 301, 305 (6th Cir. Jan. 22, 2016) (citing *Brazos*). As such, Rule 30(b)(6) provides a recognized exception to the personal knowledge requirement set forth in Rule 602.

Although Rule 30(b)(6) refers by its terms to depositions, courts have recognized that a 30(b)(6) witness may testify at trial despite a lack of personal knowledge about the matters described.

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HON. JUDGE DAN A. POLSTER

OMNIBUS REPLY IN SUPPORT OF DISTRIBUTOR DEFENDANTS' MOTIONS IN LIMINE

I. INTRODUCTION

AmerisourceBergen, Cardinal Health, McKesson, and Henry Schein (collectively, "Distributors") hereby reply to Plaintiffs' responses to Distributors' Motions in Limine. As with their opposition to the omnibus Defendants' motions in limine, Plaintiffs' opposition (while long on pages) is short on substance and contains nothing that calls into question the correctness of the in limine rulings Distributors request.

II. REPLIES IN SUPPORT OF MOTIONS IN LIMINE

1. [D-1] The Court Should Preclude Plaintiffs from Offering Evidence of, or Arguments about, Distributors' Settlements with the DEA and West Virginia.

Distributors' motion seeks a ruling that precludes evidence and arguments about settlements with the DEA and West Virginia. In response, Plaintiffs say that, of course, a settlement may be admissible if it is offered for a purpose *other than to prove liability*. Opp. 54. But it is plain as day that Plaintiffs intend to offer the DEA and other settlements to prove liability because whenever Plaintiffs have cited the settlements—most notably in their Complaints and summary judgment motions—it has been as evidence that Defendants failed to implement effective systems to prevent diversion. Distributors' motion cited seven examples of this from Plaintiffs' summary judgment papers alone. Thus, there is no mystery about Plaintiffs' purpose in discussing the settlement agreements, and Federal Rule of Evidence ("Rule") 408 forbids the use of settlements for that purpose.

¹ Distrib. MIL at 2 (citing Dkt. Nos. 1910-1 at 69–71, 81–82, 88, 93, 105–11, 113, 119–22). At these pages, Plaintiffs assert that Cardinal Health's 2012 DEA settlement "admitted that it failed to comply with the requirements of the CSA"; that McKesson's 2008 DEA settlement "Confirms the Lack of CSA Compliance"; that McKesson's 2017 DEA settlement "Admitted It Violated the Requirements of the CSA from 2009-2017"; that ABDC's 2007 DEA settlement was an agreement "to stop shipping suspicious orders in violation of the 'shipping duty'"; and that Walgreen's 2013 DEA settlement "admitted that it had failed to comply with its obligations under the CSA."

Plaintiffs argue that the DEA settlements were about "some other claims" than those at issue in this trial, and that Rule 408 therefore does not even apply. Opp. 53 (citing *Uforma/Shelby Bus. Forms, Inc. v. N.L.R.B.*, 11 F.3d 1284 (6th Cir. 1997).² Distributors agree that the settlements were about "some other claims," but that does not help Plaintiffs—instead, it underscores that the settlements are irrelevant and any reference to them would be based on a "if it happened there, it must be happening here" premise. Distrib. MIL at 4–5. As noted, Plaintiffs repeatedly cite the settlements as evidence that Defendants did not have compliant suspicious-order monitoring systems—the very claim in this case.³

Nor does Rule 406 provide a backdoor to admissibility. *First*, the settlements do not establish that Distributors "engaged in 'systematic, particularized, and repetitive conduct' by selling prescription opioids without proper, effective controls to prevent diversion." Opp. 56. Settlements are not adjudications, and these settlement agreements did not contain factual findings. Three of the six settlements did not include admissions of any kind, and the other three contained narrow admissions that did not implicate distribution of opioids to Cuyahoga or Summit Counties. Distrib. MIL at 5. *Second*, even if the settlements did "establish" facts, neither one settlement (in the case of ABDC and Walgreens) nor two (Cardinal Health and McKesson) over a period of 20 years reflects a "routine" practice.⁴ And the settlements, which do not concern distributions to Cuyahoga and Summit Counties, certainly do not establish that

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² The *Uforma/Shelby* decision (and the excerpt from Wright & Miller on which it relies) concerned a very different issue—whether Rule 408 protects a wrong committed in the course of the settlement discussions. Specifically, in *Uforma/Shelby*, the issue was whether evidence of management's threats of retaliation in the course of settlement discussions of a labor grievance could be used, apart from the grievance, to prove an unfair labor practice claim for retaliating against the union's filing of the grievance. 111 F.3d at 1293–94.

³ As noted below, Plaintiffs' argument regarding the settlement agreements is internally inconsistent. If it is true, as Plaintiffs claim later in their opposition, that the settlements "concern[] the same violations alleged here," then Rule 408 plainly prohibits their admissibility.

⁴ See Opp. 56 (noting that Cardinal Health's and McKesson's second DEA settlements were "roughly a decade later"). In the case of McKesson, moreover, its SOM system changed materially in the intervening decade, further undermining any assertion of a "pattern."

the particular conduct of any Distributor was routine practice as to either county.⁵ *Third*, Plaintiffs misunderstand the purpose of Rule 406, which is to use proof of routine practice to show what happened in a particular case. Thus, in the case cited by Plaintiffs, the defendant sought to prove that it gave the negligent driver its standard rental agreement by showing that it was a matter of routine practice to provide that document to rental customers. *Martin v. Thrifty Rent A Car*, 1998 WL 211786, at *5 (6th Cir. Apr. 23, 1998) (citation omitted). Here, by contrast, Plaintiffs have disclaimed any intention to prove that a particular prescription was medically unwarranted or that a particular pharmacy order was suspicious, electing to proceed with aggregate proof.

Plaintiffs' next argument—that the settlements are relevant—contradicts its initial arguments, Opp. 53–54, that Rule 408 does not apply because the settlements concern "some other claim" and are offered for a purpose other than to prove liability. Plaintiffs argue that the DEA settlements describe "investigations and findings ... concerning the same violations alleged here." Opp. 57 (emphasis added). And Plaintiffs misleadingly add that the agreements "apply to all (or at least most) distribution centers." Opp. 57–58 (citing only one McKesson and one ABDC settlement). But while the prospective aspects of the settlement agreements may in some instances have applied to all of the Distributor's distribution centers, the investigations that gave rise to the agreements did not concern all centers—and did not concern the centers that distributed to Cuyahoga and Summit Counties. Distrib. MIL at 5.

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⁵ The very case that Plaintiffs rely on makes clear that the Rule 406 inquiry "require[s] some comparison of the number of instances in which any such conduct occurs with the number in which no such conduct took place," and further instructs that "before a court may admit evidence of habit, the offering party must establish ... more than a mere 'tendency' to act in a given manner, but rather, conduct that is 'semi-automatic' in nature." *Bell v. Consol. Rail Corp.*, 299 F. Supp. 2d 795, 800 (N.D. Ohio 2004). For that very reason, the *Bell* court excluded generalized evidence that the defendant routinely provided locomotives with inoperable defrosters or required trains to run at track speed in foggy conditions. *Id.* at 801.

⁶ In making their relevance argument, Plaintiffs refer once to "findings" and twice to "violations" of CSA "duties." Opp. 57. The settlement agreements do not make findings and did not adjudicate violations.

Plaintiffs also argue that the settlements are admissible to prove "state of mind"—that "Defendants' conduct was intentional and persisted over a lengthy period of time." Opp. 55. But none of the settlements admits any *intentional* conduct and, as explained above, the small number of isolated agreements over a 20-year period hardly establishes a lengthy course of conduct. Plaintiffs' argument that the settlements are admissible to show Distributors' "state of mind"—*i.e.*, an alleged "pattern of conduct demonstrating knowledge by Defendants that their SOM systems were inadequate"—is similarly unavailing: the settlement do not contain admissions of any conduct relevant to Cuyahoga and Summit Counties and do not establish a pattern.

Finally, Plaintiffs argument that admission of the settlement agreements would not be unfairly prejudicial is flat-out wrong. Although inaccurate, it is plain that Plaintiffs intend to portray the settlement agreements as establishing that Distributors violated the CSA. While they blithely assert that "the jury is not likely to believe that an agreement with the government to settle what are in effect charges for CSA violations amount to an admission of liability to the alleged RICO [and] OCPA" claims, Plaintiffs have made clear that they intend to argue to the jury that supposed "CSA violations" are RICO/OCPA predicate acts. It is difficult to imagine anything more prejudicial than the (false and misleading) suggestion to the jury that the federal government already has found Distributors liable for the very statutory violations that lie at the heart of Plaintiffs' claims (as they conceive them). See, e.g., Stockman v. Oakcrest Dental Ctr., P.C., 480 F.3d 791, 800, 805 (6th Cir. 2007) (noting the "profound" impact "of evidence regarding a settlement agreement with regard to a determination of liability").

⁷ Distributors do not agree that Plaintiffs have identified any provisions of the CSA whose violation would constitute a RICO predicate act.

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

Track One Cases

MDL 2804

Case No. 17-d-2804

Hon. Dan Aaron Polster

WALGREENS' MOTIONS IN LIMINE

II. Motion No. W-2: To preclude evidence or argument about Walgreens' Florida DEA enforcement action and related settlement

Walgreens moves *in limine* to preclude plaintiffs from offering evidence or argument about a DEA enforcement action and administrative settlement agreement involving a single Walgreens distribution center in Florida that last shipped controlled substances to Ohio in 2007. Walgreens also moves to exclude reference to the \$80 million Walgreens paid to the DEA to settle the DEA's allegations while litigation was pending and before any adjudication of the allegations by a court or other factfinder.

Plaintiffs allege that Walgreens improperly distributed prescription opioid medication to its retail pharmacy stores in Cuyahoga and Summit Counties and thereby contributed to an oversupply of opioids that caused them harm. Given their near-exclusive reliance in their complaint and summary judgment papers on allegations specific to Florida, it is apparent that plaintiffs intend to argue that the unproven (and disputed) allegations in an Order to Show Cause/Immediate Suspension Order issued to a Walgreens distribution center in Jupiter, Florida ("Florida OTSC") somehow show that Walgreens improperly distributed prescription opioid medications in Ohio.² Walgreens further anticipates that plaintiffs will suggest—and the jury may infer—that Walgreens' settlement of DEA's allegations is an admission of fault. Any such evidence or argument would be irrelevant and improper. Allowing plaintiffs to inject it into the trial would be unfairly prejudicial to Walgreens and confusing to the jury. It will lead to a

² Walgreens also moves to exclude evidence or argument about (1) Orders to Show Cause issued by DEA to six Walgreens pharmacies in Florida for alleged dispensing violations and (2) a 2011 settlement agreement involving alleged dispensing violations at a Walgreens pharmacy in California. In addition to the other arguments set forth in this motion, plaintiffs do not assert any *dispensing* claims against Walgreens in Track One, further eliminating any relevance and dramatically increasing the risk of unfair prejudice and confusion.

lengthy trial-within-a-trial about issues that have nothing to do with plaintiffs' Ohio distribution claims. The Court should exclude it under Rules 402, 403, and 408.

First, this is exactly the kind of evidence that courts routinely reject under Rules 408 and 403. Rule 408 directly "bars the admission of settlement agreements when offered 'to prove or disprove the validity . . . of a disputed claim." United States v. Tevis, 593 F. App'x 473, 476 (6th Cir. 2014) (quoting Fed. R. Evid. 408). Under Rule 408, evidence of both the existence and content of prior settlement agreements is inadmissible to prove liability on a later civil claim. In Hobart Corp. v. Dayton Power & Light Co., the court rejected plaintiffs' attempt to establish that the defendant had assumed certain liabilities because its corporate predecessor had made "admission[s]" in a settlement agreement resolving a separate case involving a different site.

2017 WL 5956911, *19-20 (S.D. Ohio Nov. 29, 2017). Because plaintiffs were "attempting to use evidence of a prior settlement agreement to establish . . . liability and prove the validity of a disputed . . . claim," the evidence was "inadmissible under Rule 408." Id. at *21. As the court explained, "making the content of prior settlement agreements available for use in related litigation contravenes the very purpose of Rule 408." Id.³

Evidence about settlement agreements is likewise inadmissible under Rule 403 as unduly prejudicial. As the Sixth Circuit has recognized, "the potential impact of evidence regarding a settlement agreement with regard to a determination of liability is profound." *Stockman v. Oakcrest Dental Ctr.*, *P.C.*, 480 F.3d 791, 800 (6th Cir. 2007). The same is true here. Were evidence of Walgreens' settlement with DEA admitted, the jury would likely conclude that

³ Rule 408's clear bar on settlement evidence also serves to prevent the introduction of irrelevant evidence under Rule 402, since "disputes are often settled for reasons having nothing to do with the merits of a claim." *Korn, Womack, Stern & Assocs., Inc. v. Fireman's Fund Ins. Co.*, 27 F.3d 566, 1994 WL 264263, at *6 (6th Cir. 1994); *see also Bridgeport Music, Inc. v. Justin Combs Pub.*, 507 F.3d 470, 480 (6th Cir. 2007) ("[A] settlement offer or the fact of settlement negotiations is not direct evidence regarding the factual issues in a case.").

Walgreens must have acted improperly if it paid a significant sum of money to resolve DEA's allegations, without ever determining whether plaintiffs have proved their actual claims in this case. No limiting instruction is sufficient to cure the resulting prejudice. *Id.* at 805 (rejecting the proposition "that any amount of evidence supporting liability, . . . coupled with a limiting instruction . . . is sufficient to cure the wrongful admission" of settlement evidence).

The Florida OTSC is similarly inadmissible. The document contains preliminary unproven allegations and improper legal conclusions, about a single distribution center in Florida, that were never tested in adversarial proceedings before an administrative law judge. These very same characteristics have led courts to reject the suggestion that government "investigation[s]" or "sanctions" against one member of a corporate family are "indicative of [wrongdoing] on a company-wide scale," *Loos v. Immersion Corp.*, 762 F.3d 880, 889 (9th Cir. 2014), and to hold that "an SEC enforcement action" is "not evidence of fraud, or even negligence or mistake," *Se. Pa. Transp. Auth. v. Orrstown Fin. Servs., Inc.*, 2016 WL 7117455, at *11 (M.D. Pa. Dec. 7, 2016). The Florida OTSC "do[es] not prove that any of the conduct described therein actually occurred or, if it did occur, the conduct was [unlawful]." *Chen v. Mayflower Transit, Inc.*, 315 F. Supp. 2d 886, 923 (N.D. Ill. 2004). As for the Florida OTSC's legal opinions, "questions of law are not a proper subject for evidentiary proof." *Id.*; *see also* Dkt. No. 2494 (granting in part defendants' motion to exclude opinions of James Rafalski as legal conclusions).

Second, the Florida OTSC and settlement agreement are irrelevant and misleading for a separate reason: plaintiffs have not established any evidentiary nexus, through expert testimony or otherwise, between distribution activity in Florida and either of the Track One counties. It is not disputed that the distribution center in Florida that was the subject of the Florida OTSC did not distribute any controlled substances to Ohio after January 2007—years before any of the

events in Florida that led to the Florida OTSC. Unsurprisingly, Plaintiffs and their experts do not identify a single allegedly "suspicious order" shipped from Florida into either Cuyahoga or Summit County. Even if they had, Plaintiffs have never identified any even remotely similar issues involving Walgreens stores in Cuyahoga or Summit County, much less in the relevant time period. Any hypothetical connection is attenuated beyond the point of speculation.

Whether the policies and procedures at the distribution center in Florida were the same as at other Walgreens distribution centers does not change the analysis. Plaintiffs will have to prove at trial what the systems were at the relevant distribution centers that shipped prescription opioid medications to Walgreens pharmacies in Track One during the relevant time period. They will also have to demonstrate that the systems at the relevant distribution centers did not comply with the law. The DEA's disputed opinions about whether the systems at a Florida distribution center violated the law—at a time when that distribution center was not shipping to the Track One counties—are neither relevant nor proper. *See Chen*, 315 F. Supp. 2d at 923.

Finally, if the Court were to permit evidence and argument regarding the Florida OTSC and subsequent settlement, Walgreens would be forced to introduce the evidence necessary to rebut the DEA's allegations, requiring a whole trial in itself. In fact, prior to settlement, the allegations in the Florida OTSC were set to be tried for 18 days in a hearing before an administrative law judge in agency proceedings with hundreds of exhibits and dozens of fact and expert witnesses specific to the circumstances in Florida. See Exhibit C (Notice of Hearing in DEA ALJ Proceedings); see also Exhibit D (Government Prehearing Statement); Exhibit E (Walgreens Prehearing Statement). To litigate these factual disputes now, years later, would be a massive distraction and misuse of the jury's time. Moreover, with eight defendants remaining in the Track One trial, and only 100 hours for all defendants to put on their defense, Dkt. No. 2594 at 1-2, there is simply no time for evidence related to collateral issues in other states.

The Court should exclude all evidence and argument relating to DEA's OTSC and Walgreens' subsequent settlement agreement.

III. Motion No. W-3: To preclude, e.g., evidence or argument referring to DEA witness Joseph Rannazzisi as the "60 Minute Man"

Walgreens moves *in limine* to preclude evidence or argument suggesting that former DEA Deputy Administrator Joseph Rannazzisi's credibility or character is bolstered by the fact of his appearance on 60 Minutes, in articles published by the Washington Post, or in reporting by any other news organization. At deposition, plaintiffs' counsel repeatedly referred to Mr. Rannazzisi as the "60 Minute Man," going so far as to create a hand-drawn demonstrative "Roadmap" that started on "60 Minute Man Road," and continued from there to focus extensively on Mr. Rannazzisi's appearance on the television news program, as well as his interviews in the Washington Post. *E.g.*, **Exhibit F**, Rannazzisi Dep. 376:19-377:9; 396:11-399:6.

Walgreens anticipates that plaintiffs may seek to paint Mr. Rannazzisi as an honest whistleblower by virtue of these news appearances, including in opening statement. Such references would trade on the credibility of respected news organizations—and those organizations' purported commitment to finding and reporting the truth—to suggest that Mr. Rannazzisi is also credible by virtue of the fact that these organizations reported what he said. (By the same token, the fact that 60 Minutes or any news article criticized a company or individual should not be used to impeach that person.) That improperly invades the jury's role as factfinder to weigh the strength of the evidence. It also threatens to mislead and confuse the jury in a way that is prejudicial to Walgreens and other defendants. Any such evidence or argument should be excluded under Rule 403.

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

MDL 2804

OPIATE LITIGATION

Case No. 17-md-2804

This document relates to:

Hon. Dan Aaron Polster

Track One Cases

Plaintiffs' Omnibus Response to Defendants' Motions *In Limine* (Dkts. #2645, #2648, #2653, #2661, #2663, #2666, #2668) and Memorandum in Support

October 7, 2019

2. <u>Walgreens' MIL No. W-2</u>: To preclude evidence or argument about Walgreens' Florida DEA enforcement action and related settlement.

The arguments asserted by Walgreens regarding admissibility under Rule 408 and 403 are addressed in § B.1, *supra*. Rule 408 does not preclude this evidence, and it is both relevant and not unfairly prejudicial.

With regard to Walgreens' argument that evidence concerning the Florida DEA enforcement action should be excluded because it occurred in Florida, rather than Ohio, this argument ignores the well-known problem of opioid "migration" from one location to another. As the Washington Post recently reported,

During the past two decades, *Florida became ground zero for pill mills* — pain management clinics that served as fronts for corrupt doctors and drug dealers. They became so brazen that some clinics set up storefronts along I-75 and I-95, advertising their products on billboards by interstate exit ramps. So many people traveled to Florida to stock up on oxycodone and hydrocodone, they were sometimes referred to as "prescription tourists."

The route from Florida to Georgia, Kentucky, West Virginia and Ohio became known as the 'Blue Highway." It was named after the color of one of the most popular pills on the street — 30 mg oxycodone tablets made by Mallinckrodt, which shipped more than 500 million of the pills to Florida between 2008 and 2012.

When state troopers began pulling over and arresting out-of-state drivers for transporting narcotics, drug dealers took to the air. One airline offered nonstop flights to Florida from Ohio and other Appalachian states, and the route became known as the Oxy Express.

"76 billion opioid pills: Newly released federal data unmasks the epidemic," The Washington Post, July 16, 2019 (emphasis added).⁷¹

There is abundant evidence in the record – including in Walgreens' own internal documents – that the opioids the Defendants shipped migrated far beyond the borders of the states to which the shipments were made, including, oftentimes, to Ohio, and that Defendants were well aware of this phenomenon. *Supra* at fn.37. Defendants were regularly alerted to the migration phenomenon

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⁷¹ Available at https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html (accessed on 10/3/19).

by the DEA, and their personnel acknowledged the reality of diversion and migration in their depositions. *Supra* at fns.39-40.

Against this robust record of diversion and migration, of which the above-cited materials are only examples, Walgreens' assertion of the lack of a nexus between their irresponsible shipment practices and harm to the CT-1 Plaintiffs rings hollow. Defendants shipped hundreds of millions of opioid pills to resellers throughout the U.S. They knew that those resellers could, and often did, sell those opioids to individuals who had come long distances from Ohio or elsewhere to obtain pills they could in turn sell at a substantial profit back home. That every diverted pill posed a risk to localities throughout the nation was not only foreseeable to Walgreens, it was observed and known by them. Each shipment Walgreens made in disregard of the potential for diversion is evidence of damages caused by Walgreens to localities throughout the nation, including Cuyahoga and Summit Counties.

Because the potential for diversion is so great and its consequences so pernicious, each Defendant was required to establish and maintain a SOM program. Plaintiffs have catalogued the numerous flaws in the SOMs operated by Defendants. Each Defendant's SOM was implemented nationally; no special procedures were followed with respect to the CT-1 jurisdictions or elsewhere. Because of the uniform national character of Defendants' SOMs, each wrongful order filled by Defendants is further evidence of the flaws in Defendants' SOMs, and of the consequences of those flaws. Defendants' efforts to exclude this highly probative evidence, including by Walgreens' MIL No. W-2, should be denied.

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

Track One Cases

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

WALGREENS' REPLIES IN SUPPORT OF ITS MOTIONS IN LIMINE

evidence of Walgreens' equity ownership interest in ABDC under Rule 403.

II. W-2: To exclude Walgreens' Florida DEA action and related settlement¹
Plaintiffs' response to Walgreens' second motion in limine fails for several reasons.

First, Rule 408 directly bars use of Walgreens' Florida settlement with DEA to prove plaintiffs' claims. MIL at 5-6. Plaintiffs attempt to avoid Rule 408 by suggesting that the DEA settlement involved "some other claim." Opp. at 53-54. But plaintiffs do not deny that they intend to use the settlement to prove liability in this case. In fact, they admit it just a few pages later in an effort to show that the settlement is relevant. Opp. at 57 (arguing that the settlement "concern[s] the same violations alleged here"); id. at 85 (arguing that Walgreens' shipments to Florida caused harm in Ohio). Plaintiffs are wrong about relevance, but there is no question that the purpose for which they seek to use this evidence is impermissible under Rule 408.

Second, Plaintiffs cannot save their intended misuse of Florida settlement evidence by appealing to Rule 406. Fundamentally, a rule about *relevance* cannot supersede a policy-based bar on *admissibility*. The Federal Rules plainly contemplate the exclusion of relevant evidence. See, e.g., FED. R. EVID. 403 ("The court may exclude relevant evidence if"). In any event, a *single* settlement in *Florida* could never amount to a "routine practice" in Ohio. For the same reason, plaintiffs' attempt to suggest that the settlement shows that Walgreens' conduct "was intentional and persisted over a lengthy period of time" falls flat. See Opp. at 54-57. Unlike other distributors, Walgreens did not enter multiple settlements over any length of time.²

¹ Walgreens also moved to exclude six Orders to Show Cause issued to Florida pharmacies and a 2011 settlement involving a California pharmacy—each of which involved *dispensing* allegations only. MIL at 4 n.2. Plaintiffs have not opposed that request. That aspect of Walgreens' motion should be granted regardless of the Court's ruling on the settlement and Order to Show Cause relating to Walgreens' Florida distribution center.

² Plaintiffs incorporate by reference their arguments in § B.1 of their omnibus response. Opp. at 84. Walgreens likewise incorporates the distributors' reply in support of Dkt. 2666, MIL D-1.

Third, the Florida settlement and OTSC are, in fact, irrelevant. The fact of settlement says nothing about the merits of the underlying allegations. MIL at 5 n.3 (collecting authority). Courts have rejected the suggestion that government investigations or even sanctions are evidence of wrongdoing. Id. at 6 (collecting authority). And that is on top of the fact that the allegations about conduct in Florida have no connection to plaintiffs' Ohio claims. Plaintiffs' response involves generalized assertions about pill "migration," Opp. at 84-85, and a truly remarkable notion that any evidence that Walgreens' improperly shipped a suspicious order anywhere is evidence of damages everywhere, id. at 85. But plaintiffs do not (and cannot) dispute that neither they nor their experts have established any evidentiary nexus between distribution in Florida and either of the Track One counties. MIL at 6-7.

Fourth, plaintiffs' answer to Walgreens' arguments about prejudice under Rule 403 is to baldly assert that jurors are unlikely to conclude that Walgreens' settlement of alleged "CSA violations" is an admission of liability for plaintiffs' claims based on alleged CSA violations.

See Opp. at 59. Plaintiffs' argument makes no sense, and flies directly in the face of the Sixth Circuit's view that the impact of settlement evidence is "profound" and no amount of evidence of liability, even with a "limiting instruction," is "sufficient to cure [its] wrongful admission."

Stockman v. Oakcrest Dental Ctr., P.C., 480 F.3d 791, 800, 805 (6th Cir. 2007).

Finally, plaintiffs offer no response at all to the unfair prejudice of introducing the Florida OTSC's preliminary, unproven allegations and improper legal conclusions. MIL at 6. Nor do they dispute that the introduction of evidence about the OTSC or subsequent settlement would require a whole trial in itself, wasting valuable time and confusing the jury. *Id.* at 7.

III. W-3: To exclude references to Joseph Rannazzisi as the "60 Minute Man"

In response to Walgreens' motion to exclude evidence or argument referring to DEA witness Joseph Rannazzisi as the "60 Minute Man," plaintiffs admit that they plan to use such

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

| IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION |)) | |
|--|-------|---|
| This document relates to: <i>The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.</i> Case No. 18-op-45090 |)))) | MDL No. 2804 Hon. Judge Dan A. Polster |
| and |) | |
| The County of Cuyahoga v. Purdue Pharma L.P., et al. Case No. 1:17-op-45004 |))))) | |

TEVA DEFENDANTS' AND ACTAVIS GENERIC DEFENDANTS' <u>OMNIBUS MOTION IN LIMINE</u>

Pursuant to Federal Rules of Evidence 402, 403, 404, and 408, and for the reasons set forth in the Teva Defendants' and Actavis Generic Defendants' (collectively, "Moving Defendants") attached Memorandum of Law, Moving Defendants move for the following to be excluded at trial:

- TAD-1: reference to the Cephalon misdemeanor plea;
- TAD-2: reference to "off-label" promotion;
- TAD-3: reference to the 2008 civil settlement between Cephalon and the Office of Inspector General (along with the settlement of the opioid action brought by the Oklahoma Attorney General);
- TAD-4: evidence of any opioid-related harm that occurred outside of the Counties;
- TAD-5: evidence of marketing-related statements or opioid shipments outside of the Counties;

whether Defendants' conduct constituted off-label activity is to force the jury into an irrelevant, confusing and highly prejudicial mini-trial.

Accordingly, any testimony, evidence, and argument that Cephalon, Teva USA, or any of the other Moving Defendants engaged in off-label promotion should be excluded.

C. The Court Should Exclude Any Reference To The 2008 Civil Settlement Between Cephalon And The Federal Government (TAD-3).

Plaintiffs have made repeated references to a settlement that Cephalon entered into with the Department of Justice in 2008 for claims of off-label marketing (the "Cephalon Settlement"). *See* Summit TAC ¶ 787; Opp., at 10. There was no admission of liability. *See* Cephalon Settlement, attached as Ex. 3, at II.L. Evidence of that settlement, along with any other civil settlements, 4 must be excluded for two separate and independent reasons.

First, Rule 408 precludes introduction of settlement agreements "to prove or disprove the validity or amount of a disputed claim." Fed. R. Evid. 408; see also Korn, Womack, Stern & Assocs., Inc. v. Fireman's Fund Ins. Co., 27 F.3d 566, 1994 WL 264263, at *6 (6th Cir. June 15, 1994) (evidence tending to show acceptance of valuable consideration in compromise of a disputed claim "is inadmissible if it is offered to show the invalidity of the plaintiff's claim or the liability of the defendant."). By the plain language of Federal Rule of Evidence 408(a), evidence of the Cephalon Settlement is inadmissible to show liability, because that settlement involved paying "consideration in compromising . . . the claim[s]" against it. Fed. R. Evid. 408(a)(1); see also United States v. Robinson, No. 5:11CR00584, 2012 WL 5386037, at *3 (N.D. Ohio Nov. 2, 2012)

This includes the settlement that the Moving Defendants entered into with the Oklahoma AG in connection with the Oklahoma Action (the "Oklahoma Settlement"). That Oklahoma Settlement is also barred by Rule 408, Rule 402, and Rule 403.

(applying Rule 408 to exclude evidence of settlement); *Day v. NLO, Inc.*, 798 F. Supp. 1322, 1330 (S.D. Ohio 1992) ("Rule 408 bars evidence of both settlement and settlement negotiations.").

Recognizing the critical purpose of promoting settlements, the Sixth Circuit has explained that "[i]t would be unreasonable to expect a party to ever make a settlement offer if doing so forced it into choosing between conceding one or more elements of liability or damages or having the offer admitted against it." *Stockman v. Oakcrest Dental Ctr.*, *P.C.*, 480 F.3d 791, 798–99 (6th Cir. 2007). If Plaintiffs had their way, however, the Cephalon Settlement (and any other settlement agreement involving the Moving Defendants), would become fodder for liability determinations in this trial, thus removing the cloak of protection that attaches to settlements in order to promote the efficient resolution of disputes.

Second, the Cephalon Settlement is irrelevant. The Cephalon Settlement resolved civil claims (pertaining to alleged off-label promotion) based upon different allegations, legal theories, and time periods than are at issue in this case. It did not have anything to do with conduct specific to Summit or Cuyahoga County. Moreover, there was no admission of liability. Thus, the Cephalon Settlement is not relevant to any determination to be made by the jury. *See Bridgeport Music, Inc. v. Justin Combs Pub.*, 507 F.3d 470, 480 (6th Cir. 2007) (quoting *Urseth v. City of Dayton*, 680 F. Supp. 1084, 1098 (S.D. Ohio 1987) ("[A] settlement offer or the fact of settlement negotiations is not direct evidence regarding the factual issues in a case.").); *Cent. Reg'l Emps. Ben. Fund v. Cephalon, Inc.*, No. 09-3418 MLC, 2009 WL 3245485, at *4 (D.N.J. Oct. 7, 2009) (dismissing false marketing claims against pharmaceutical manufacturer of opioid medicines notwithstanding allegation that manufacturer previously entered into settlement).

Lastly, even if the evidence of the Cephalon Settlement were otherwise admissible (and it is not), the evidence should be excluded under Fed. R. Evid. 403. *See Stockman*, 480 F.3d at 799

(holding settlement evidence inadmissible under Rule 403 in addition to Rule 408); *see also Goodyear*, 332 F.3d at 982–83 ("the statement [made in furtherance of settlement] would likely be inadmissible under Rules 403 and 408"). Rule 403 permits the Court to exclude even "relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury" Fed. R. Evid. 403.

That is precisely the case here. If evidence of the Cephalon Settlement were admitted, the jury is likely to conclude—wrongly—that Cephalon acted improperly because it paid significant sums of money to resolve civil actions regarding marketing practices, without ever determining whether the plaintiffs proved their *specific* claims *in this case*. This unwarranted conclusion also may be extended to the other Moving Defendants by affiliation. Indeed, a jury may believe—wrongly—that if Cephalon did nothing wrong, it would not have settled. This risk of unfair prejudice is "profound." *See United States v. Hays*, 872 F.2d 582, 589 (5th Cir. 1989) ("[T]he potential impact of evidence regarding a settlement agreement with regard to a determination of liability is profound. It does not tax the imagination to envision the juror who retires to deliberate with the notion that if the defendants had done nothing wrong, they would not have paid the money back."), *cited with approval in Stockman*, 480 F.3d at 800. The Cephalon Settlement (as well as the Oklahoma Settlement) should be excluded.

D. The Court Should Exclude Evidence Of Opioid-Related Harm That Occurred Outside Of The Counties (TAD-4).

This Court should prohibit any evidence regarding any harm that occurred outside of Ohio.

As a matter of law, the Counties can only recover for any harm that *they* incurred.⁵ As a result,

⁵ 18 U.S.C. § 1962(c) (under RICO, plaintiff must be injured "in his business or property"); Ohio Rev. Code Ann. § 2923.34 (OCPA limits standing to "person who is injured"); *Lawyers Title Co., LLC v. Kingdom Title Sols., Inc.*, 592 F. App'x 345, 355 (6th Cir. 2014) ("if a plaintiff suffers no actual damages

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

MDL 2804

OPIATE LITIGATION

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Track One Cases

Plaintiffs' Omnibus Response to Defendants' Motions *In Limine* (Dkts. #2645, #2648, #2653, #2661, #2663, #2666, #2668) and Memorandum in Support

October 7, 2019

excessive promotion of opioids created a public health crisis. Aggressive overpromotion of dangerous drugs need not be fraudulent to be unlawful. Evidence regarding Moving Defendants' promotion of their opioids for a multitude of uses beyond those approved is fundamentally relevant to Plaintiffs' claims in this case. *See* Dkt. #2000-8 (Kessler Expert Rep.).

Moving Defendants also argue that FDA regulations are "arcane," *id.* at p. 5, and "risk sucking the jury down an irrelevant rabbit hole of confusion and side issues." *Id.* at p. 4. But the jury is not tasked with determining whether Moving Defendants' conduct violated FDA regulations surrounding off-label promotion or whether certain communications were protected speech, and it need not do so in order to determine whether Defendants' conduct substantially contributed to the opioid epidemic. Moving Defendants raise the specter of "an irrelevant, confusing and highly prejudicial mini-trial," but the jury need not "assess[] whether Defendants' conduct constituted off-label activity[.]" *Id.* at pp. 5-6. The question is whether Moving Defendants' conduct in aggressively over-promoting their opioid products (whether for approved or off-label uses) was a substantial factor in causing the harms caused by overprescribing alleged by Plaintiffs. Answering this question does not require determining whether Defendants' off-label promotion complied with FDA regulations. Evidence, testimony, and argument regarding Moving Defendants' promotion of drugs for uses beyond the approved indications are relevant and should not be excluded.

3. <u>Teva MIL No. TAD-3</u>: The Court should exclude any reference to the 2008 civil settlement between Cephalon and the Federal Government.

The arguments asserted by Moving Defendants in their MIL No. TAD-3 are addressed in § B.1, *supra*. Rule 408 does not preclude this evidence, and it is both relevant and not unfairly prejudicial.

4. <u>Teva MIL No. TAD-4</u>: The Court should exclude evidence of opioid-related harm that occurred outside of the counties.

Moving Defendants seek to prohibit any evidence regarding harm that occurred outside of Ohio, on the theory that the Plaintiffs can only recover for harm that they incurred. As initial matter, it is unclear what Moving Defendants mean by "evidence of harm," and hence exactly what

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

This document relates to:

Case No. 17-md-2804

Track One Cases

Hon. Dan Aaron Polster

TEVA DEFENDANTS' AND ACTAVIS GENERIC DEFENDANTS' REPLY IN SUPPORT OF THEIR OMNIBUS MOTION IN LIMINE

Manufacturers' cases holding that claims of off-label marketing were preempted, because in those cases courts "held that a claim based solely on off-label promotion was preempted, but claims for fraud not"); see also Summit R. & R., ECF No. 1025 at 50 (denying off-label preemption argument because Plaintiffs "contend that Defendants misrepresented the risks associated with off-label opioid use."). Now, Plaintiffs contend that evidence of off-label marketing is relevant to their theory that Moving Defendants engaged in "overpromotion" of opioid medications. Opp. at 105. Plaintiffs cannot have it both ways. They cannot avoid dismissal and summary judgment by arguing that their claims are not based upon off-label promotion, yet now argue that such conduct is relevant. It is not. See Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc., No. 13-71672014 WL 2115498, at *6 (E.D. Pa. May 21, 2014) (rejecting claims based upon allegations of off-label promotion against Cephalon and Teva USA).

C. The Court Should Exclude Any Reference To The 2008 Civil Settlement Between Cephalon And The Federal Government (TAD-3).

Plaintiffs' Opposition does not respond specifically to TAD-3; instead, it refers to its response to Distributors' motion to preclude Plaintiffs from offering evidence of certain settlements. Opp. at 106. Plaintiffs' arguments have no application to the Moving Defendants. Because they do not address this argument, the motion should be granted. *Estate of Ardt by Parker v. Allstate Ins. Co.*, No. 09-14247, 2011 WL 13208693, at *1 (E.D. Mich. Nov. 9, 2011) ("To the extent that plaintiff failed to present any argument in response to a particular issue, plaintiff has conceded the point.").

As an initial matter, Plaintiffs argue that Rule 408 does not bar evidence of settlement of a claim from being used to prove a distinct claim in the future. Opp. at 53–54. Plaintiffs, however, conflate the standard for admissibility of statements made during the course of compromise

negotiations with the standard for admissibility of settlement agreements. While the former (compromise negotiations) may be used in some limited instances to prove the validity of a distinct claim (such as one that arises during the negotiations themselves),³ the latter (settlement) may not be used to prove the validity of a distinct claim. *See Korn, Womack, Stern & Assocs., Inc. v. Fireman's Fund Ins. Co.*, 27 F.3d 566 (6th Cir. 1994) (evidence of the settlement of claims would be inadmissible to prove the validity of "distinct" claims); *United States v. Robinson*, No. 5:11CR00584, 2012 WL 5386037, at *3 (N.D. Ohio Nov. 2, 2012) (applying rule). Accordingly, this principle has no bearing on the instant motion, which seeks to exclude a settlement agreement, with no admission of liability, unconnected to the Counties. Rule 408 prohibits Plaintiffs from introducing evidence of the Cephalon Settlement to prove their claims in this case.

Plaintiffs argue that courts have recognized several purposes allowing for the admission of settlement evidence; namely, establishing a party's knowledge of potential harm and proving a party's state of mind. Opp. at 54–55. However, Plaintiffs do not argue (nor can they) that either purpose is served through the Cephalon Settlement. As to knowledge of potential harm, Plaintiffs argue that "the multitude of enforcement actions and settlements establish a pattern of conduct demonstrating knowledge by Defendants that their SOM systems were inadequate." *Id.* at 55. Cephalon's single settlement for off-label marketing is entirely unrelated to any SOM systems, any knowledge about SOM systems, or even any relevant conduct in the Counties; it certainly cannot be said to establish a pattern. The same failing befalls Plaintiffs' argument that the "enforcement actions demonstrate that Defendants' conduct was intentional and persisted over a lengthy period of time." *Id.* Thus, the only explanation that remains is the obvious one—that

Plaintiffs' cases support this rule. *See Uforma/Shelby Bus. Forms, Inc. v. N.L.R.B.*, 111 F.3d 1284, 1293 (6th Cir. 1997); *Gjokaj v. United States Steel Corp.*, 700 F. App'x 494, 501 (6th Cir. 2017).

Plaintiffs intend to introduce the Cephalon Settlement to prove their clams, in violation of Rule 408.

D. The Court Should Exclude Evidence Of Opioid-Related Harm That Occurred Outside Of The Counties (TAD-4).

Plaintiffs do not dispute that their experts do not cite to any studies regarding opioid-related harms that occurred *in* the Counties and instead rely on documents and studies examining *other* municipalities and states, or national studies with generalized conclusions that cannot be extrapolated to the Counties. Opp. at 107; *see also* Mot. at 8–9. Nor do Plaintiffs dispute that they plan to rely at trial on documents, statistics, and studies demonstrating harms that are *entirely outside* of Cuyahoga and Summit Counties as evidence of the "national scope and nature of the crisis" in order to prove their alleged injuries. *Id.* Instead, Plaintiffs appear to argue that they should be allowed to introduce such evidence because '[t]his is a crisis which many Defendants are disputing actually exists" and "Defendants [may] blame the Plaintiffs for the harms." *Id.* 4 But Plaintiffs do not cite to anything on the record to support those assertions. Moreover, those arguments make little sense and are simply a red herring.

At trial, the Counties can only recover for any harm that *they* incurred.⁵ The Court has made abundantly clear that only harm to the Counties is at issue. Dkt. No. 2561, at 4-6 (denying summary judgment based upon alleged "increase in the supply of prescription opioids in the *Track One* Counties"). And Plaintiffs even concede in their Opposition that they "cannot recover for

Inc., 592 F. App'x 345, 355 (6th Cir. 2014) ("if a plaintiff suffers no actual damages from the underlying unlawful act, there can be no successful civil conspiracy action") (citation and quotation omitted); *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 480 (6th Cir. 2017) (common law public nuisance claim requires injury to plaintiff).

Plaintiffs rely on *Royal Park Investments SA/NV v. U.S. Bank Nat'l Ass'n*, No. 14CIV2590VMJCF, 2017 WL 4748054 (S.D.N.Y. Oct. 19, 2017), but that case is neither controlling nor is it applicable as the issue there was valuation of a bank's assets for damages and did not consider whether damages of non-party banks should be included.

18 U.S.C. § 1964(c) (under RICO, plaintiff must be injured "in his business or property"); Ohio Rev. Code Ann. § 2923.34 (OCPA limits standing to "person who is injured"); *Lawyers Title Co., LLC v. Kingdom Title Sols.*,